Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation clinical consequence of fistulectomy with or with out immediate sphincteroplasty in the treatment of anal fistula

Protocol summary

Study aim
Comparison of fistulectomy surgery with sphincterolasty in the treatment of anal fistula

Design
In order to randomly allocate the samples to two groups, a simple random method will be used, which is determined by the qualified patient's referral based on the entry and exit criteria, and by using a table of random numbers and selecting even or odd numbers for the allocation of the patient to the relevant group. The study is blinded from the point of view of the patients and the evaluator, and the patient and the evaluator are not aware of the possible outcomes and complications after the operation, but the surgeon is.

Settings and conduct
The intended study will be a single-blind randomized clinical trial on patients referred to Imam Khomeini Hospital in Sari during the years 1401-1402.

Participants/Inclusion and exclusion criteria
1.Patients with anal fistula referred to Imam Hospital in the age range of 15-80 years 2.Consent to participate in the study

Intervention groups
Patients with anal fistula referred to Imam Hospital in the age range of 15-80 years

Main outcome variables
Gas and stool incontinence Recurrence rate Duration of surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221211056784N1**
Registration date: **2022-12-26, 1401/10/05**
Registration timing: **registered_while_recruiting**
Last update: **2022-12-26, 1401/10/05**
Update count: **0**

Registration date
2022-12-26, 1401/10/05

Registrant information

Name
Akram Kalani sarokolaie

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 4204 1154

Email address
akram.kalani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-12, 1401/09/21

Expected recruitment end date
2023-05-20, 1402/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation clinical consequence of fistulectomy with or with out immediate sphincteroplasty in the treatment of anal fistula

Public title
Fistulectomy with or with out primery repair

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with anal fistula in 15_80 age

Exclusion criteria:

Pregnancy History of anal surgery Coagulation disorder

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

By calculating the sample size, taking into account a certain number of patients, they will be divided into two equal groups, the number of measurement times is 4 times. The sample collection is based on the goal and based on the entry and exit criteria. In order to randomly allocate the samples to two groups, a simple random method will be used, which is determined by the qualified patient's referral based on the entry and exit criteria, and by using a table of random numbers and selecting even or odd numbers for the allocation of the patient to the relevant group. The study is blinded from the point of view of the patients and the evaluator, and the patient and the evaluator are not aware of the possible outcomes and complications after the operation, but the surgeon knows.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to randomly allocate the samples to two groups, a simple random method will be used, which is determined by the qualified patient's referral based on the entry and exit criteria, and by using a table of random numbers and selecting even or odd numbers for the allocation of the patient to the relevant group. The study is blinded from the point of view of the patients and the evaluator, and the patient and the evaluator are not aware of the possible outcomes and complications after the operation, but the surgeon is.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sari University of Medical Sciences

Street address

Imam khomeini hospital., Amir mazandarani Ave .,Sari., Iran

City

Sari

Province

Mazandaran

Postal code

4764647343

Approval date

2022-03-16, 1400/12/25

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1401.002

Health conditions studied

1

Description of health condition studied

Anal fistula

ICD-10 code

K60.3

ICD-10 code description

Anal fistula

Primary outcomes

1

Description

Recurrence rate

Timepoint

One week, two weeks, 1, 3, 6 and 12 months after the surgery, the patients are re-examined and they are studied in recurrence rate

Method of measurement

through a questionnaire

2

Description

Gas and stool incontinence

Timepoint

One week, two weeks, 1, 3, 6 and 12 months after the surgery

Method of measurement

through a questionnaire

3

Description

Postoperative satisfaction rate

Timepoint

One week, two weeks, 1, 3, 6 and 12 months after the surgery

Method of measurement

through a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: primary sphincteroplasty after fistulectomy in this group after fistulectomy is performed simultaneously in the same primary tissue repair operation with thread. And the results of this type of tissue repair, including the rate of recurrence and incontinence, are compared with the control group
Category
Treatment - Surgery

2

Description
Control group: fistulectomy without sphincteroplasty. In this group, after sphincterotomy, the tissue defect is repaired in a secondary way and over time, and there is no intervention after sphincterotomy for repair.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Sari
Full name of responsible person
akram kalani
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Imam khomeini hospital., Amir mazandarani Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran university of medical science
Full name of responsible person
Dr. Pedram Ebrahim Nehad
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Imam khomeini hospital., Amir mazandarani Ave
.,Sari., Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran university of medical science
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Akram kalani
Position
General surgery resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Position
General surgery resident

Latest degree
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Other areas of specialty/work
General Surgery

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Person responsible for updating data

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General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available